UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader
January 15, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
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January 12, 1999

MEMORANDUM

SUBJECT: ***PHASE 2 - ERROR CORRECTION.*** Response to Comments on EPA's Ethyl Parathion Draft Health Effects Division Chapter of the Reregistration Eligibility Decision Document. PC Code: 057501

FROM: Nicole C. Paquette, Ph.D.
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THRU: Alan Nielsen, Branch Senior Scientist 1/12/99
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TO: Susan Lewis, Branch Chief
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The attached errata list for ethyl parathion was generated in response to the document *Comments on EPA's Ethyl Parathion Draft Health Effects Division Chapter of the Reregistration Eligibility Decision Document* (December 8, 1998) submitted by Cheminova Agro A/S in Phase 1 of the Public Participation Process. The errata list is to accompany the HED chapter entitled; *Ethyl Parathion. Dietary and Occupational Risk Assessments* (memo from Griffin to Sproat-10/28/98). Some of the comments concern issues and/or Agency policy and will more appropriately be dealt with during Phase 4.

Ethyl parathion ERRATA

This memo serves to correct errors (Phase 2) made in the disciplinary chapters written for the ethyl parathion Reregistration Eligibility Document (RED), completed October 1998. This is in response to comments made on errors in Phase 1 of the Public Participation Process. Some of the comments made by the registrants do not address errors, but rather issues and policy, and will be addressed, as appropriate, in Phase 4.

A. ERRORS IN EPA'S MAY 21, 1998, MEMORANDUM TITLED "PARATHION (057501). THE OUTCOME OF THE HED METABOLISM ASSESSMENT REVIEW COMMITTEE MEETING HELD ON MARCH 11, 1998" (p. 10 of Comments on EPA's Ethyl parathion)

1, 2, 3. These issues will be deferred until Phase 4.

B. ERRORS IN EPA'S MAY 21, 1998, MEMORANDUM TITLED "OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND RECOMMENDATIONS FOR THE REREGISTRATION ELIGIBILITY DECISION DOCUMENT FOR ETHYL PARATHION (p. 11 of Comments on EPA's Ethyl parathion)

1. HED will correct this error during the response phase to public comments.

2. There are several end-use products containing both ethyl parathion and methyl parathion. HED will correct this error during the response phase to public comments.

3. This statement was not intended to refer to submitted studies in disciplines other than the occupational and residential exposure assessments. This statement will be emended to refer specifically to occupational exposure studies in HED's response to public comment phase.

4. At the time that this memorandum was written, using labels provided by the registrant (EPA Reg. No. 4787-16), the maximum application rate on wheat and barley was 0.75 lbs a.i. per acre.

5. HED does not believe that the inclusion of poisoning incidents is an error.

C. ERRORS IN EPA'S MARCH 30, 1998, MEMORANDUM TITLED "REVIEW OF PARATHION INCIDENT REPORTS" (p. 11-12 of Comments on EPA's Ethyl parathion)

1, 2, 3. These issues will be deferred until Phase 4.

D. ERRORS IN EPA'S UNDATED MEMORANDUM TITLED "ETHYL PARATHION. DIETARY AND OCCUPATIONAL RISK ASSESSMENTS" (p 12,13,14 of Comments on EPA's Ethyl parathion)

2. HED does not consider this statement to be an error.

6. HED does not consider this statement to be an error.

12. HED does not consider this statement to be an error.

E. ERRORS IN EPA'S SEPTEMBER 10, 1998, MEMORANDUM TITLED "ANTICIPATED RESIDUE ESTIMATES BASED ON AVAILABLE MONITORING DATA" (p.14, 15, 16 of Comments on EPA's Ethyl parathion)

1 - 6 These issues will be deferred until Phase 4

F. ERRORS IN EPA'S MARCH 25, 1998, MEMORANDUM TITLED "ETHYL PARATHION - REPORT OF THE HAZARD IDENTIFICATION ASSESSMENT REVIEW COMMITTEE" (p 19, 20, 21, 22 of Comments on EPA's Ethyl parathion)

1 The statement on page 6 will read, "Residential uses for ethyl parathion are prohibited. Therefore, the following risk assessment is applicable only for occupational exposures."

2 On pages 11, 13 and 14 the footnotes referenced in the text correspond to literature citations. All referenced footnotes will be added to the memo.

3 The correct purity for ethyl parathion in the acute oral neurotoxicity study in rats (MRID 43117901) should be 86.2%.

4 a. The Agency concurs with the suggestions on sentence(s) clarification.
b. The Agency acknowledges and concurs with the calculated RBC and brain cholinesterase percent activity compared with controls. The percent cholinesterase activity will not have any impact on the Agency's conclusions of the study and does not impact the risk assessment. The corrections will be made during Phase 4, as appropriate.

5 a. The sentence should read; ... "plasma cholinesterase activity was significantly depressed for both sexes (males; 73-36 % of control; females 85-44% of control)."
b. While EPA concurs that the 15% inhibition of cholinesterase activity in females given 0.01 mg/kg of ethyl parathion is not statistically significant, EPA disagrees 15 % inhibition is not biologically significant because clearly this is a dose related

effect in females as well as males and is reflected in the RBC cholinesterase inhibition at all doses in both sexes.

c. The statement regarding the decrease in brain cholinesterase in females given 0.03 mg/kg will remain.

6 A. The doses in the 180-day study in dogs were; 0.0024, 0.0079 and 0.7937 mg/kg; the mid dose is 0.0079 mg/kg. In the 3rd paragraph, "rats" should be changed to "dogs".

D. The first statement in the first sentence of the 3rd paragraph is accurate; " Plasma cholinesterase activity was reduced as early as Week 1 and markedly reduced by Week 6 and throughout the rest of the study in both males and female dogs given 0.079 [0.0079] and 0.7937 mg/kg." There is no mention of statistical or biological significance. Furthermore, percent inhibition of cholinesterase activity is not calculated for Week 1 and not mentioned. The 1st sentence is an observation of an inhibitory effect which increases over the 6-month study period. The Agency agrees that in plasma cholinesterase activity was not statistically significantly decreased in female dogs at any dose. Nevertheless, there was a dose related decrease in plasma cholinesterase activity in female dogs given 0.0079 mg/kg at Weeks 6, 14 and 26. Furthermore, a dose related decrease was observed in females given 0.7937 mg/kg throughout the study.

E. The 4th sentence of the same paragraph should read, "There was a slight reduction in RBC cholinesterase activity in both male and female dogs given 0.7937 mg/kg; 18% for both sexes compared to control values.

7. The Agency acknowledges the conversions of ppm to mg/kg based on body weight and food consumption. The test substance intake will not have any impact on the Agency's conclusions of the study and does not impact the risk assessment. The corrections will be made during Phase 4, as appropriate.

8. The recommended editorial changes to the last paragraph will be made during Phase 4.

9. The sentence should read, "In an acute neurotoxicity study (MRID 43117901), male rats given a single oral doses of 10 mg/kg of ethyl parathion had only partial reversibility of brain ChE inhibition with concomitant incomplete recovery from abnormal FOB measures and cholinergic signs in two of eight males at 14 days post dose."

10. The sentences on page 10 and 14 should read, " ethyl parathion caused retinal degeneration/atrophy and sciatic nerve degeneration in female and male rats (respectively) given the highest dose (females; 2.47 and males;1.75 mg/kg).

11. Typographical error noted; doses = dose

12. The purity of the active ingredient tested in the rat and rabbit developmental study was 99.11%; LOT AK-1144.

H. Errors in EPA's May 27, 1998, memorandum titled "Residue Chemistry Chapter for the Parathion Reregistration Eligibility Decision (RED) Document" (p. 22-25 of Comments)

1, 6. The Agency acknowledges that Cheminova's end-use product registration numbers have changed: Subsequent to the issuance of the Residue Chemistry Chapter, Cheminova Agro A/S transferred their end-use products to Cheminova, Inc., a subsidiary of Cheminova Agro A/S. In order to amend the Chapter (at this time) to include this info, the Agency needs to verify that use profiles on the "new" labels are the same as those on the "old" labels. This will be addressed in Phase 4.

2, 3, 4, 5, 9, 10,11, 13, 14, 17. A number of studies have been received by the Agency and are in review. These data will be addressed during Phase 4, as appropriate.

7, 8, 12, 16, 18, 19, 20. HED does not consider these statements to be errors.

15. On page 11 of the Residue Chemistry Chapter, in the table entitled "Calculation of maximum dietary burdens of livestock animals for parathion", there are actually two typos. The % Dry Matter and Tolerance for corn stover in the Dairy Cattle calculation should be 83 (not 89) and 20 (not 25), respectively. The Dietary contribution calculation (3.6 ppm) is correct, however. These typos had no impact on the dietary risk assessments for parathion.